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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,253	02/09/2006	Nagarajan Kuppuswamy	2070.1001	5990

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WASHINGTON, DC 20005

EXAMINER
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CHO, JENNIFER Y

ART UNIT	PAPER NUMBER
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1621

MAIL DATE	DELIVERY MODE
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10/10/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/535,253	<b>Applicant(s)</b> KUPPUSWAMY ET AL.	
	<b>Examiner</b> JENNIFER Y. CHO	<b>Art Unit</b> 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **Detailed Action**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/8/08 has been entered.

Claims 1-12 and 14-20 are pending in this application.

### **Claim Rejections – 35 USC 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 and 14-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no evidence in the record

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for the amended claim language of “a ratio ranging from 4.54-19.64 : 3.88-15.64 : 1 (v/v)”, at the time of filing the application.

Additionally, the suggested amendment to claim 1, adding the limitation for “a ratio ranging from 4.54-19.64 : 3.88-15.64 : 1 (v/v)”, raises an issue of new matter. Applicant refers to examples 1-10 in the specification, however, ratios from the examples is not sufficient. The Applicant's have not shown an explicit teaching or contemplation for the ratios in the specification. This amounts to a new concept that was not present at time of filing.

### **Claim Rejections - 35 USC 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 and 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peverali et al. (US 6,518,456), in view of Cannata et al. (US Patent Publication 2004/0068011).

Peverali et al. teaches a process for the preparation of gabapentin by preparing an aqueous solution of gabapentin hydrochloride in water in the ratio of one part by weight of gabapentin hydrochloride to 2.3 part by weight of water (column 5, lines 30-32, example 6). An 30% sodium hydroxide aqueous solution is then added to the gabapentin solution at a temperature of 23°C to adjust the pH to 7.1 to 7.2 (column 5, lines 33-36, example 6). The solution is heated to 50°C to 55°C then to 60°C to 65°C (column 5, lines 38-41, example 6). The solution is then cooled to 10°C to 15°C and then aged to keep the precipitate solution at this temperature for a period of one hour (column 5, lines 42-43, example 6). The precipitate is separated by centrifugation (column 5, lines 44, example 6) and recrystallized with water and ethanol to give gabapentin in 99.7 % purity, with additional mother liquor (column 5, lines 44-67, example 6).

Peverali et al. is deficient in the sense that it does not teach recrystallization of the precipitate from a mixture of isopropyl alcohol, methanol and water.

Cannata et al. teaches the purification and recrystallization of gabapentin with isopropyl alcohol, methanol and water (page 2, section 28).

As far as the temperature levels, the percentage of alkali metal base, the solvent ratios and the chloride content, it is the position of the examiner that one of ordinary skill in the art, at the time of the invention, would through routine and normal

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experimentation determine the optimization of these limitations to provide the best effective variable depending on the results desired. Thus it would be obvious in the optimization process to optimize the temperature, alkali metal percentage, solvent ratios and the chloride content of Gabapentin. The applicant does not show any unusual and/or unexpected results for the limitations stated. Note that the prior art provides the same effect desired by applicant, the preparation of gabapentin with over 99.5% purity.

Therefore, it would be prima facie obvious to one of ordinary skill in the art at the time of the invention, to select suitable temperatures and percentages, since it is well-known that a variety temperatures and alkali metal percentages can be used to neutralize a gabapentin hydrochloride solution. Absent any showing of unusual and/or unexpected results over applicant's particular limitations for the addition of a sodium hydroxide solution to gabapentin hydrochloride, the art obtains the same effect on the purity of gabapentin. The expected result would be an improved process for the preparation of gabapentin with high purity.

### **Response to Arguments**

Applicant's arguments have been considered but are not persuasive for the following reasons:

The Examiner acknowledges Applicant's argument that in the present invention there is no digestion of acetone step.

However, the Examiner contends that Applicant's "consists essentially of" limitation does not limit the steps to exclude acetone digestion. Thus the art still reads on the claims as drawn.

The Examiner acknowledges Applicant's argument that Peverali does not teach a solvent system of IPA, methanol and water.

In response, the Examiner points to Cannata et al. which was used to explicitly teach the use of methanol and isopropyl alcohol in the recrystallization method (page 2, section 28). In addition, it is reasonable to expect that water would be present in the alcohol solutions, particularly since Cannata does not explicitly state the solvents are anhydrous. Thus the art reads on applicant's claims.

The Examiner acknowledges Applicant's argument that the terminology of "consists essentially of" disallows ethanol recrystallization.

However, the Examiner contends that Applicant's "consists essentially of" limitation does not limit the steps to exclude ethanol use. Thus the art still reads on the claims as drawn.

The Examiner acknowledges Applicant's argument that there is no support for the Examiner's assertion that water would be present in the alcohol solutions.

In response, the Examiner has included the specification sheets from Sigma-Aldrich for methanol, which states that water is present in approximately 0.1% or 5%, and for isopropyl alcohol, which states that water is present in approximately 0.2%.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Y. Cho whose telephone number is (571) 272 6246. The examiner can normally be reached on 9 AM - 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on (571) 272 0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Cho  
Patent Examiner  
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/SHAIENDRA - KUMAR/  
Primary Examiner, Art Unit 1621